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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,567	05/12/2005	Jean-Francois Biegun	CAC.P0046	6534
7590 02/04/2008 Edward G Greive Renner Kenner Greive Bobak Taylor & Weber Fourth Floor First National Tower Akron, OH 44308-1456			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 02/04/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/534,567

Applicant(s)

BIEGUN ET AL.

Examiner

Nicholas Woodall

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12, 13 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 13 and 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This action is in response to applicant's amendment received on 11/16/2007.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Merrill (U.S. Publication 2003/0119935).

Regarding claim 21, Geisser discloses a device comprising protrusions, i.e. teeth, made of a plastic material, for example polyethylene, which is to come into contact with the part of bone and rasp it from the remaining bone, wherein the plastic is hard enough to remove the bone. Geisser discloses the device is intended to be use once and will not require cleaning or sterilization after use (column 1 lines 61-63). Geisser fails to disclose the device being manufactured from a plastic capable of deteriorating when placed in an autoclave at a temperature of at least 137 degrees Celsius. Merrill teaches a device comprised of a radiation treated ultra high molecular weight polyethylene, which can be treated with gamma radiation (page 1 paragraph 10), that has a melting point of 137 degrees Celsius (page 4 paragraph 051) in order to improve the wear resistance of the device (page 1 paragraph 09). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Geisser wherein the device is manufactured from a radiation

treated ultra high molecular weight polyethylene in view of Merrill in order to improve the wear resistance of the device.

Further regarding claim 21, the combination of Geisser and Merrill disclose a device capable of deteriorating and no longer being used when put into an autoclave set at least to 137 degrees Celsius. Regarding claim 20, the combination of Geisser and Merrill disclose a device inherently capable of being used by a method comprising the steps of providing a body having the shape of a rasp and comprising protrusions made of plastic material which are to come into contact with the part of the bone and rasp it from the remaining bone when said rasp is used to remove the part of the bone and exposing the said plastic material to beta or gamma radiation, so that after this exposition, the plastic material is hard enough to remove the part of the bone when the rasp is used, and when said rasp is put into an autoclave set to at least 137 degrees Celsius the rasp deteriorates itself and cannot be used anymore.

4. Claims 12, 13, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisser (U.S. Patent 5,454,815) in view of Merrill (U.S. Publication 2003/0119935) further in view of Judd (U.S. Patent 1,396,934).

Regarding claim 15, the combination of Geisser and Merrill disclose a device wherein the plastic material of the device maybe reinforced by at least one insert at least partially embedded in the plastic material, such as carbon fibers, as discussed by Geisser (column 3 lines 7-12). The combination of Geisser and Merrill fail to disclose the insert comprising a material harder than bone, such as metal. Judd teaches a device comprising a plastic body comprising a metallic insert fully embedded in the

plastic material in order to reinforce the plastic material. Because both the combination of Geisser and Merrill and Judd teach device comprising plastic reinforcing inserts made from specific materials, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute one insert material for another in order to achieve the predictable result of providing an insert for reinforcing a plastic material.

Regarding claim 16, the combination of Geisser, Merrill, and Judd disclose a device wherein the at least one insert is fully embedded in the plastic material.

Regarding claims 17 and 18, the combination of Geisser, Merrill, and Judd disclose a device wherein the at least one insert is metal. Regarding claim 12, the combination of Geisser, Merrill, and Judd disclose a device inherently capable of being used by a method as discussed above further comprising the step of embedding at least one insert of material harder than bone in the plastic material. Regarding claim 13, the combination of Geisser, Merrill, and Judd disclose a device inherently capable of being used by a method as discussed above wherein the at least one insert is fully embedded in the plastic material.

Regarding claim 19, the combination of Geisser, Merrill, and Judd disclose the invention as claimed except for the device comprising a part, such as the insert, comprising a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made manufacture the combination of Geisser, Merrill, and Judd wherein the insert comprises a memory shape material, since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

***Response to Arguments***

5. Applicant's arguments with respect to claims 12, 13, and 15-21 have been considered but are moot in view of the new ground(s) of rejection. The examiner has presented new grounds of rejection as necessitated by the amendment making this office action **FINAL**.

***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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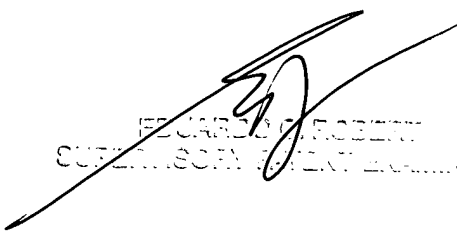
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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